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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,248

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Elliot Altman

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EXAMINER

DUFFY, PATRICIA ANN

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,248	Applicant(s) ALTMAN ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-17-08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 21-29, 32-35 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 21-29 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-17-08</u> | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment filed 11-17-08 has been entered into the record. Claims 9-20, 30-31 and 36-42 have been cancelled. Claims 1-8, 21-29, 32-35 and new claim 43 are pending. Claims 1-8, 21-29 and 32-35 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claim 43 drawn to peptidomimetic, a specie of invention nonelected with traverse in the response filed 3-3-08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Maintained

Claims 5, 8, 22-26 and 32 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Low et al (WO 90/12096, published October 18, 1990; of record) is maintained for reasons made of record.

Applicant's arguments have been carefully considered but are not fully persuasive. Applicants argue that the method provides for the presence of a membrane-permealbilizing agent and that peptidomimetic is removed. *This is persuasive for claims 1-4, 6, 7 and 21.* All other claims do not cite the reagent and applicants arguments are not persuasive for those. Applicants argue that Low et al does not determine whether the biotinolated compound has an antimicrobial effect on the cell. This is not persuasive, this method step of "determining" is seen to include those screening steps for compounds that have antimicrobial activity and those that do not. In this case, Low et al determined that the compound did not have an antimicrobial activity, since the compound protected against something with anti-microbial activity and therefore did not have an antimicrobial effect

on the cell. Applicants are narrowly construing the claimed invention, contrary to the broadest reasonable interpretation.

Claims 1-8, 22-26, 29 and 32-35 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dargis et al (Antimicrobial Agents and Chemotherapy, 38(5):973-980, 1994; of record) is maintained for reasons made of record.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue that the biotinylated antibiotic is not internalized into the cell cytosol because it binds the cell membrane. This is not persuasive because the compound is internalized pass the outer-membrane, the cell membrane is acknowledged as not being the barrier and the lactam binds the cell membrane. Further, Dargis et al did not study the amount in the cytosol. As such, broadly construed the biotinylated compound gets into the cell and interently into the cytosol, absent convincing evidence to the contrary. The biotinylated compound is taken up by the cell as it enters across the outer membrane barrier and the definition includes antimicrobial compounds. The method of the prior art provides for a compound that meets the limitation of the claim and the same steps and as such meets the limitation of the claims.

Claim 1, 2, 5, 8, 21-26, 29 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Low et al (WO 90/12096, published October 18, 1990) is maintained for reasons made of record in the Office Action Mailed 6-16-08.

Applicant's arguments have been carefully considered but are not fully persuasive. Applicants argue that the method provides for the presence of a membrane-permealbilizing agent and that peptidomimetic is removed. *This is persuasive for claims 3, 4, 6 and 7.*

All other claims do not cite the reagent and applicants arguments are not persuasive for those. Applicants argue that all cells are different and one would not

expect plants/mammals and bacterial/prokaryotics would function similarly with respect to uptake of foreign matter. This is not persuasive because the claims are not drawn to mammalian cells or plants and it is an assertion unsubstantiated by evidence that biotin transporters in these other areas do not exist and is contrary to the prior art of record indicating that mammalian cells have facilitated biotin transport of molecules.

Furthermore, Low teaches/exemplifies bacteria and *E.coli* in particular which is known to the art and moreover has a characterized biotin transporter. Applicants argue that Low et al does not determine whether the biotinylated compound has an antimicrobial effect on the cell. This is not persuasive; this method step of "determining" is seen to include those screening steps for compounds that have antimicrobial activity and those that do not. In this case, Low et al determined that the compound did not have an antimicrobial effect, since the compound protected against something with anti-microbial activity and therefore did not have an antimicrobial effect on the cell. In the absence of this broad interpretation, the skilled artisan would have to *a priori* know or devine that the compound had an antimicrobial effect. Applicants are narrowly construing the claimed invention that the determining step only reads on the situation where the compound has an anti-microbial effect, contrary to the broadest reasonable interpretation of the claims in light of the specification.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Low et al (WO 90/12096, published October 18, 1990) as applied to claims 1-8, 21-26, 29 and 32-35 above, and further in view of Kim (US Patent No 6,322,788 issued November 27, 2001) is maintained for reasons made of record.

Applicants argue that there is no evidence that the antibody conjugate is internalized by the combination. This is not persuasive because there is no evidence that it is not under the conditions as combined. Applicants argue a number of different limitations that are simply not in the claims.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is prima facie indefinite in that the term "peptidomimetic" lacks antecedent basis in the independent claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner